

REMARKS/ARGUMENTS

Claims 1-28 are pending. Claim 1 is amended to state that the step of crystallizing olanzapine is conducted in a solvent mixture which comprises 2-propanol and an effective amount of form I of olanzapine as seeding crystals. Support for the amendment can be found at, for example, paragraph 0031 of the published version of the present application. No new matter is added. Furthermore, as explained below, even if claim 1 is not amended as proposed above, the rejection of claim 1 and its dependent claims should still be withdrawn. The above amendment to claim 1 is to place the claims in better format. Therefore, Applicants respectfully request that the Examiner enter the above amendments after the final Office Action.

Applicants gratefully note that in view of Applicants' previously submitted response dated October 16, 2008, the Examiner has withdrawn the anticipation rejection of claim 23. No other rejection is raised with respect to claim 23 in the Office Action. Therefore, like claims 6-9, 12-22, 24, and 26-28, which, as explicitly stated by the Examiner, are allowable, claim 23 should also be allowable.

The only outstanding rejection in the Office Action is directed to claims 1-5, 10, 11, and 25, which are all rejected under 35 U.S.C. § 102(b) as being anticipated by Bunnell et al., U.S. Patent 5,703,232. Applicants respectfully traverse.

I. Anticipation Rejection of Claims 1-5 in View of Bunnell under 35 U.S.C. § 102(b)

Claims 1-5 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bunnell.

Claims 1-5 are directed to a process for the preparation of form I of olanzapine, comprising the step of crystallizing olanzapine in a solvent mixture which comprises 2-propanol and an effective amount of form I of olanzapine as seeding crystals.

In rendering the anticipation rejection of claims 1-5, the Examiner quotes column 1, lines 58-62 of Bunnel, which states: “The present invention provides a process for preparing **anhydrous Form I comprising contacting a lower alcohol solvate with a solvent selected from** the group consisting of ethyl acetate, **2-propanol**, t-butanol, tetrahydrofuran, and toluene.”
(Emphasis added.)

However, Bunnell’s designation of different anhydrous olanzapine polymorphs is different from the designation used by other references, such as EP-B-733635. Specifically, **Form I discussed in Bunnel is actually form II defined in the present application**. The present application adopts the definition of Form I and Form II provided in EP-B-733635. *See* paragraph 0011 of the published version of the present application. As indicated by the information disclosure statement attached with the Office Action dated August 14, 2007, the Examiner has considered EP-B-733635, which was submitted by Applicants previously. As shown at paragraph 0004 of EP-B-733635 and the Table bridging columns 3-4 of Bunnel, the anhydrous Form I of olanzapine discussed in Bunnel is actually Form II of EP-B-733635 and the present application. Likewise, as shown at paragraph 0009 of EP-B-733635 and the Table starting at line 15 of column 4 of Bunnel, the anhydrous Form II of olanzapine discussed in Bunnel is actually Form I of EP-B-733635 and the present application.

Bunnel fails to disclose any method of making Form II (i.e., Form I of EP-B-733635 and the present application), not to mention any specific process as described in claim 1 of the present application. Therefore, for at least this reason, claim 1, and claims 2-5, each of which depends from claim 1, are not anticipated by Bunnel under 35 U.S.C. §102(b).

Moreover, to place the claims in better format, claim 1 has been amended to further recite that the solvent mixture comprises an effective amount of form I of olanzapine as seeding crystals.

The new limitation provides further basis that claims 1-5 are not anticipated by Bunnell under 35 U.S.C. §102(b). Applicants respectfully request that the rejection of claims 1-5 be withdrawn.

II. Anticipation Rejections of Claims 10-11 and 25 in View of Bunnell under 35 U.S.C. § 102(b)

Claims 10-11 and 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bunnell.

As explained in Applicants' previous response dated October 16, 2008, claims 10-11 are directed to **2-propanol solvate** of olanzapine. Although Bunnell discloses methanol, ethanol, and 1-propanol solvates (*See*, for example, columns 5-7, Tables 1-3 and columns 15-16, Examples 1-6), it does not disclose, suggest, or teach a 2-propanol solvate of olanzapine and process of making thereof. Therefore, claims 10-11 are not anticipated by Bunnell under 35 U.S.C. § 102(b).

Nor would Bunnell render the solvate recited in claims 10-11 obvious, because as stated in Bunnell, "The formation of solvates is known to be an individualistic effect. The ability of a given compound to form a solvate is not predictable, to Applicant's knowledge."

Claim 25 is directed to a process for preparing anhydrous forms of olanzapine by drying at least one solvate according to claim 10. As stated above in connection with claim 10, Bunnell does not anticipate or render obvious the solvate recited in claim 10. Therefore, for at least the same reasons discussed above in connection with claim 10, claim 25 is also patentable in view of Bunnell.

The Examiner does not provide any comments on Applicant's above arguments. Nor does the Examiner provide any reason why claims 10-11 and 25 are anticipated by Bunnell. Please note that unlike claims 1-5, which are directed to form I of olanzapine, claims 10-11 and 25 are directed to 2-propanol solvate of olanzapine. Regardless of whether the Examiner's rejection of claims 1-5 is valid, the rejection of claims 1-5 cannot be equally applied against

claims 10-11 and 25, which are directed to a different subject matter. Withdrawal of the rejection of claims 10-11 and 25 in view of Bunnell under 35 U.S.C. §102(b) is, therefore, respectfully requested.

Based on the foregoing, Applicants believe that the present application has been placed in condition of allowance. Early and favorable consideration is respectfully requested.

If any additional fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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